Alabama Medicaid Agency

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ROBERT BENTLEY
Governor

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R. BOB MULLINS, JR., MD
Commissioner

February 13, 2012

Pharmacy Name
Address
City, State, Zip

RE: DESK REVIEW
Provider: Provider Number

Dear Pharmacy Manager:

Goold Health Systems, on behalf of the Alabama Medicaid Agency, will conduct a desk review audit of pharmacy records from Pharmacy Provider as a provider of blood clotting factor in agreement with Alabama Medicaid to meet Rule No. 560-X-16-.31 "Hemophilia Management Standards of Care". Pursuant to prescriptions and refills dispensed for Patient Names, please complete Form A (one copy per pharmacy) and submit required documentation as instructed in Form B for each client included in this audit.

It is requested that these documents be submitted electronically on a CD-ROM. The CD-ROM should be sent by certified mail to the address noted below. If you are unable to submit electronic copies of these documents, hardcopies are acceptable. If you have any questions, please contact me by phone at (515) 201-2809, or e-mail at thisel@ghsinc.com. Failure to submit the requested materials within 30 days of the receipt of this letter but no later than 11:59 p.m. on March 19, 2012, or to meet any of the standards evaluated by this audit, may result in termination of your contract to provide blood clotting factor to Alabama Medicaid recipients.

Sincerely,

Tina M. Hisel, Pharm.D., BCPS
Goold Health Systems
45 Commerce Drive, Suite 5
Augusta, ME 04330

Enclosure(s):
Form A (CD-ROM)
Form B (CD-ROM)

FORM A

1. Describe your methods for shipping clotting factor and ancillary supplies to your clients. Provide specific information on your packaging practices. This should also include information on how you maintain required storage temperatures throughout the shipping process, how you ensure timeliness of delivery, and what efforts are/will be made if/when the "chain" is interrupted.

_____

_____

_____

_____

_____

_____

2. List the title(s) and format of Educational Support materials that are provided or available for your clients and that address the specific topics noted. If the manufacturer's package insert instructions are utilized for patient educational purposes, please note "Package Insert" on the line next to any applicable topic.

Injury Prevention
Title:

_____

_____

_____

□ Print	□ Audio
□ Video	□ Electronic
□ Print	□ Audio
□ Video	□ Electronic
□ Print	□ Audio
□ Video	□ Electronic

Clotting Factor Reconstitution
Title:

_____

_____

_____

□ Print	□ Audio
□ Video	□ Electronic
□ Print	□ Audio
□ Video	□ Electronic
□ Print	□ Audio
□ Video	□ Electronic

Clotting Factor Administration
Title:

_____

_____

_____

□ Print	□ Audio
□ Video	□ Electronic
□ Print	□ Audio
□ Video	□ Electronic
□ Print	□ Audio
□ Video	□ Electronic

3. Describe your methods for providing sharps and biohazard waste containers, as well as pickup and disposal of sharps/biohazard waste containers according to national, state and local biohazard waste ordinances.

4. Provide the telephone number that clients may call for 24-hour service.

5. If any client(s) served by the prescription(s) identified in this audit are no longer under your service, please identify what efforts have been made to ensure continuation of care for the client.

6. Complete the Clinical Personnel Blood Clotting Factor Continuing Education Register to list the clinical staff employed by your company or the company contracted by your facility to provide in-home care for the client(s) identified in this audit during the timeframe of January 1, 2011 to December 31, 2011. Additionally, provide the title(s) of recognized continuing education programs specific to clotting factor-related diseases and the hours provided by each program. If nursing services are contracted, forward the "Clinical Personnel Blood Clotting Factor Continuing Education Register – NURSE" form to the contracted service to complete. The completed form must be returned to Goold Health Systems.

   Pharmacists: 2 credit hours per year
   Nurses and social workers: 4 credit hours per year

Done this _____ day of _____, _____

_____(representative of pharmacy provider) I hereby certify that I have authority to bind

_____(pharmacy provider) to this agreement.

Title of above representative:_____

Address: _____

_____

_____

Phone:_____

E-mail:_____

Alabama Medicaid Agency Provider Number:_____

Notary Public:_____

Commission Expires:_____

Clinical Personnel Blood Clotting Factor Continuing Education Register – PHARMACIST (2 credit hours per year)

Pharmacist Name	Hire Date	Continuing Education	CEUs	Date
		Program Title: Program Number:		
		Program Title: Program Number:		
		Program Title: Program Number:		
		Program Title: Program Number:		
		Program Title: Program Number:		
		Program Title: Program Number:		
		Program Title: Program Number:		

Clinical Personnel Blood Clotting Factor Continuing Education Register – NURSE (4 credit hours per year)

Nurse Name	Hire Date	Continuing Education	CEUs	Date
		Program Title: Program Number:		
		Program Title: Program Number:		
		Program Title: Program Number:		
		Program Title: Program Number:		
		Program Title: Program Number:		
		Program Title: Program Number:		
		Program Title: Program Number:		

FORM B

1. **For the timeframe of January 1, 2011 to December 31, 2011, submit the following documentation for Patient Names:**
   - ☒ Copies of the yearly in-home assessment for each client, which includes an assessment of their environment.
   - ☒ Copies of the original prescription(s) written for blood clotting factor.

2. **For the timeframe of January 1, 2011 to March 31, 2011, submit the following documentation for Patient Names:**
   - ☒ Copies of the prescription labels for blood clotting factor dispensed to each client. Provide supplemental documentation regarding the quantity of blood clotting factor that was dispensed to each client if this information is not included on the label. This includes the number of units per vial and the total number of vials dispensed to reach the prescribed dose.
   - ☒ Copies of the prescription labels for medically necessary ancillary supplies dispensed to the client.
   - ☒ Copies of the shipping records (Fed Ex, UPS, etc.) for blood clotting factor and medically necessary ancillary supplies shipped to the client. If blood clotting factor and medically necessary ancillary supplies are delivered to the client by your pharmacy, please indicate this accordingly.
   - ☒ Copies of all documented phone contact with the client or family/caregiver, as well as phone contact with other care providers. As required by the Hemophilia Management Standards of Care, a case representative shall maintain, at a minimum, monthly telephone contact with the client or family/caregiver to include, but not limited to:
     - Inquiry regarding client's current state of well-being
     - Assessment of client/family compliance/adherence, and persistence with the medical treatment plan
     - Incidence of adverse events
     - Incidences of supply or equipment malfunctions
     - Home inventory check of factor and supplies
     - Confirmation of next delivery date
   - ☒ Copies of documentation regarding client adherence with blood clotting factor therapy.
   - ☒ Copies of documentation indicating the amount of blood clotting factor the client has on hand prior to dispensing the next refill.
   - ☒ Copies of documentation indicating the number of client bleeds and infusions since the previous shipment.
   - ☒ Copies of pharmacist counseling records.
   - ☒ Copies of documentation regarding the emergency delivery of blood clotting factor. If there was no emergency delivery of blood clotting factor required, indicate 'Not Applicable'.
   - ☒ Copies of documentation regarding the notification of product recalls or withdrawals. If there were no situations requiring notification of product recalls or withdrawals, indicate 'Not Applicable'.
   - ☒ Copies of documentation regarding adverse drug reactions and drug interaction monitoring/reporting. If there were no specific issues/concerns reported to physicians, indicate 'Not Applicable'.